



**SECURITY FOR YOUR
PLASMA DERIVATIVES**
Raw materials for plasma fractionation



Blood Plasma Fractionation

Human plasma contains proteins of high therapeutic value, which are prepared from the pooled plasma of many donors. They are also called plasma derivatives, i.e. concentrates of specific plasma proteins, which are obtained through a process known as fractionation.

The main fractionation steps include precipitation, purification and virus inactivation. Therefore, plasma derivatives are heat-treated and / or solvent detergent-treated to kill certain viruses like those that cause HIV or hepatitis.

Plasma derivatives include:

- Factor VIII
- Factor IX
- Anti-Inhibitor Coagulation Complex (AICC)
- Albumin
- Immunoglobulins, including Rh Immunoglobulin
- Anti-Thrombin III
- alpha 1-Proteinase Inhibitor

These proteins are used for e. g. haemophilia or autoimmune disorders treatment.

We are fully aware of the safety and quality requirements to prepare such therapeutic proteins. Therefore, PanReac AppliChem shall be your first choice as supplier of reagents for plasma fractionation.

- **High-quality raw materials** that fulfill Pharmacopoeia specifications.
- **Documentation** for register and approval available (MSDS, regulatory certification, manufacturing process).
- **Effectiveness** of the purification process guaranteed – reliably.

Raw materials for the precipitation of proteins

Whatever parameter has to be modified: pH, ionic strength or ethanol concentration, with PanReac AppliChem's reagents, you may adjust to the required conditions to precipitate the plasma proteins.

Raw materials for protein purification

Fractions obtained from plasma after precipitation are still complex mixtures and do require further purification steps. Purification techniques include:

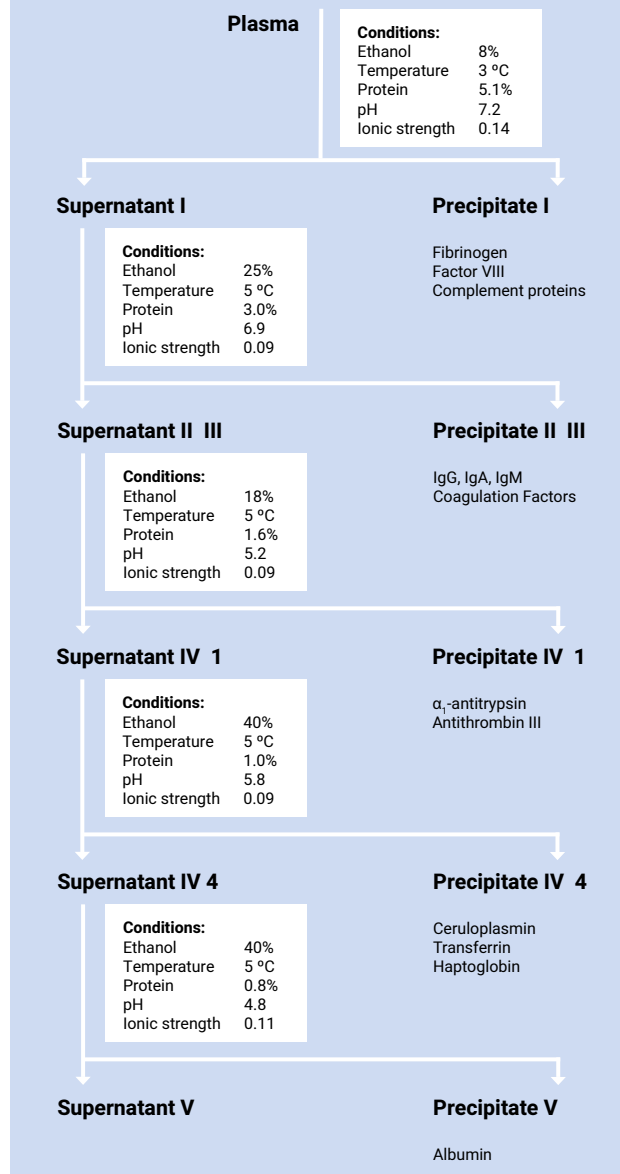
- Filtration
- Affinity Chromatography (AC)
- Immobilized metal ion affinity chromatography (IMAC)
- Size exclusion chromatography (SEC)
- Ion exchange chromatography (IEX)

A good elution is achieved by increasing the salt concentration, modifying pH and polarity, adding chaotropes and/or detergents.

Additionally, it is critical to select the appropriate buffer. Please note that the table on the next page only represents a selection of the products available.

Blood Plasma Fractionation Scheme

This reaction scheme is an example of how a plasma fractionation may be performed. The scheme was adapted from Curling, J. (2002) *BioPharm Int.* 15(10), 16-26



Raw materials for virus inactivation

The virus inactivation is an essential step to prevent contamination by viruses such as Hepatitis or HIV. Apart from a very strict control and selection of donors, some virus inactivation steps are carried out before final product release.

The chemical treatment used for virus inactivation are:

- Low pH treatment
- Pasteurization (requires a stabilizer like sucrose, glycine or sodium caprylate)
- Solvent/detergent treatment

RAW MATERIAL FOR PLASMA FRACTIONATION



Product number	Product name	CAS number	Excipient	Precipitation	Elution	Buffer Selection	Virus Inactivation
141008	Acetic Acid glacial (USP, BP, Ph. Eur., JP) pure, pharma grade	64-19-7	•	•		•	•
637763	N-Acetyl-DL-Tryptophan (Ph. Eur, BP) low endotoxin, pharma grade	87-32-1	•				
63B764	6-Aminohexanoic Acid (Ph. Eur., BP, USP) IPEC grade	60-32-2		•			
A1032	Ammonium Sulfate BioChemica	7783-20-2			•		
Z44653	L-Arginine mono-Hydrochloride (USP, BP, Ph. Eur., JP) low endotoxin pure, pharma grade	1119-34-2	•				
141808	Citric Acid anhydrous (USP, BP, Ph. Eur., JP) pure, pharma grade	77-92-9				•	
141018	Citric Acid 1-hydrate (USP, BP, Ph. Eur., JP) pure, pharma grade	5949-29-1				•	
141270	Copper(II) Sulfate 5-hydrate (BP, Ph. Eur.) pure, pharma grade	7758-99-8			•		
141669	EDTA Disodium Salt 2-hydrate (USP, BP, Ph. Eur.) pure, pharma grade	6381-92-6	•			•	
141340	Glycine (USP, BP, Ph. Eur.) pure, pharma grade	56-40-6	•		•		
A3240	Guanidine Hydrochloride ultrapure	50-01-1			•		
141020	Hydrochloric Acid 37% (USP-NF, BP, Ph. Eur.) pure, pharma grade	7647-01-0	•				
IG2108	Hydrochloric Acid 2 mol/l (2N) pharma grade	7647-01-0				•	
IG2536	Imidazole pure	288-32-4			•		
631404	Magnesium Sulfate 7-hydrate (Ph. Eur, BP) GMP - IPEC grade	10034-99-8			•		
A1074	MES 1-hydrate for buffer solutions	145224-94-8				•	
632786	Octanoic Acid (BP, Ph. Eur., USP-NF, ChP) low endotoxin, IPEC grade	124-07-2	•	•			•
Z46373	n-Octyl-β-D-Glucopyranoside pure	29836-26-8					•
141512	di-Potassium Hydrogen Phosphate anhydrous (BP, Ph. Eur.) pure, pharma grade	7758-11-4	•			•	
141509	Potassium di-Hydrogen Phosphate (USP-NF, BP, Ph. Eur.) pure, pharma grade	7778-77-0	•			•	
631632	Sodium Acetate 3-hydrate (Ph. Eur, BP, USP) IPEC grade	6131-90-4	•	•		•	•
636454	Sodium Caprylate (USP-NF, BP, Ph. Eur., ChP) low endotoxin, IPEC grade	1984-06-1	•	•			•
631659	Sodium Chloride (Ph. Eur, BP, USP) low endotoxin, IPEC grade	7647-14-5	•		•	•	
631655	tri-Sodium Citrate 2-hydrate (Ph. Eur, BP, USP) IPEC grade	6132-04-3	•			•	
IG1679	di-Sodium Hydrogen Phosphate anhydrous (USP, BP, Ph. Eur.) pure, pharma grade	7558-79-4	•			•	
141965	Sodium di-Hydrogen Phosphate 1-hydrate (USP, BP) pure, pharma grade	10049-21-5	•			•	
631687	Sodium Hydroxide pellets (Ph. Eur, BP, USP, JP) IPEC grade	1310-73-2	•	•		•	
631621	D(+)-Sucrose (USP-NF, BP, Ph. Eur.) low endotoxin, IPEC grade	57-50-1	•		•		
Z41940	TRIS (USP, BP, Ph. Eur.) low in endotoxin, pure, pharma grade	77-86-1				•	
142050	Tween® 80 (USP-NF, BP, Ph. Eur.) pure, pharma grade	9005-65-6			•		•
191754	Urea crystal (USP, BP, Ph. Eur.) pharma grade	57-13-6			•		

This is a selection of raw materials for plasma fractionation. If you have any other needs or requests, please contact us at biopharma@itwreagents.com and we will be glad to support you.



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AppliChem GmbH

Ottoweg 4 · DE-64291 Darmstadt · Germany · Phone +49 6151 9357 0 · Fax +49 6151 9357 11
info.de@itwreagents.com

ITW Reagents S.R.L.

Corso Milano, 31 · I-20900 Monza (MB) · Italy · Phone +39 039 9530 360 · Fax +39 039 9530 361
info.it@itwreagents.com

Panreac Química S.L.U.

C/ Garraf 2, Polígono Pla de la Bruguera · E-08211 Castellar del Vallès · (Barcelona) Spain
Phone +34 937 489 400 · Fax +34 937 489 401
info.es@itwreagents.com

itwreagents.com

